SKIN THERAPY CALM- colloidal oatmeal 1 % cream Harmony Herbal

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Skin Therapy CALM

Active ingredient

Colloidal Oatmeal 1%

Purpose

Skin protectant

Uses

Temporarily protects and helps relieve minor skin irritation and itching due to eczema, poison oak, ivy, or sumac, rashes, insect bites.

Warnings

For external use only.

Keep out of reach of children

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Directions: Apply to affected skin 2-3 times daily.

Inactive ingredients

Inactive ingredients: Water, Organic Aloe Barbadensis Leaf Juice, Thuja Orientalis Extract, Scutellaria Baicalensis Root Extract, Phellodendron Amurense Bark Extract, Coptis Chinesis Root Extract, Hyssopus Officinalis Extract, Atractylodes Lancea Root Extract, Lonicera Japonica Stem Extract, Dictamnus Desycarpus Root Extract, Organic Olea Europaea (Olive) Oil, Glycerin (plant derived), Cetearyl Alcohol, Cetearyl Glucoside, Caprylic Capric Triglycerides, Glyceryl Stearate (plant derived), Isopropyl Palmitate (plant derived), Niacinamide, Phenethyl Alcohol, Caprylyl Glycol, Ethylhexyl Glycerin, C10-18 Triglycerides, Allantoin, Sodium PCA, Linoleic Acid, Tocopherol.

Stop use and ask a doctor if...

Stop use and ask a doctor if symptoms worsen, or do not improve after regular use of this product as directed. Avoid contact with eyes.





SKIN THERAPY CALM

colloidal oatmeal 1 % cream

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:70597-117

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name

Basis of Strength

OATMEAL (UNII: 8PI54V663Y) (OATMEAL - UNII:8PI54V663Y)

OATMEAL

OATMEAL

1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
LONICERA JAPONICA WHOLE (UNII: UV4X7MQQ43)	
NIACINAMIDE (UNII: 25X5118RD4)	
ATRACTYLODES LANCEA ROOT OIL (UNII: EC228KGY00)	
ALLANTOIN, (+)- (UNII: XDK458E1J9)	
C10-18 TRIGLYCERIDES (UNII: 43AGM4PHPI)	
CAPRYLIC/CAPRIC/LAURIC TRIGLYCERIDE (UNII: FJ1H6M2JG9)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
COPTIS CHINENSIS ROOT (UNII: CXS4LJR7EL)	
DICTAMNUS DASYCARPUS ROOT (UNII: 6153LEN214)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
HYSSOPUS OFFICINALIS FLOWERING TOP (UNII: X7HKN4FOJI)	
WATER (UNII: 059QF0KO0R)	
LINOLEIC ACID (UNII: 9KJL21T0QJ)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 4690TG57A2)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
PHELLODENDRON AMURENSE BARK (UNII: PBG27B754G)	
PHENYLETHYL ALCOHOL (UNII: ML9LGA7468)	
SCUTELLARIA BAICALENSIS ROOT (UNII: 7J95K7ID2S)	
TOCOPHEROL (UNII: R0ZB2556P8)	
PLATYCLADUS ORIENTALIS WHOLE (UNII: 835370K47L)	

P	Packaging							
#	Item Code	Package Description	Marketing Start Date	Marketing End Date				
1	NDC:70597-117- 15	1 in 1 BOX	06/01/2017					
1		42.5 g in 1 TUBE; Type 0: Not a Combination Product						

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part347	06/01/2017		

Labeler - Harmony Herbal (071401048)

Registrant - Harmony Herbal (071401048)

Revised: 10/2021 Harmony Herbal